

## REMARKS

Claims 1 has been amended. Claims 2, 3 and 13 have been cancelled herein. Claims 1, 11-12 are pending. No new matter has been added.

Applicants thank the examiner for the thorough and thoughtful consideration of the present application and the art of record. Each of the points raised by the examiner in the 7/23/09 action are addressed below.

### **1.     Claims 1, 11 and 12 are Not Anticipated over Subramanian, 6,113,795**

Claims 1, 2, 11 and 12 stand rejected under 35 USC 102(b) as allegedly anticipated by the disclosure of Subramanian et al. (US 6,113,795 "Subramanian"). Applicants respectfully traverse all aspects of this rejection, and request reconsideration of the claims as currently presented for the reasons expressed below.

The method of Claims 1, 11 and 12 is not disclosed in Subramanian. To expedite prosecution of this case, Claim 1 has been amended to include limitations of previously found in claim 2, now cancelled.

As the examiner will appreciate, "*for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly.*" (MPEP 706.02 (emphasis added)).

Subramanian fails to anticipate Claim 1 as it fails to teach at least that "isolating said particulate pharmaceutical product from the combined supercritical fluid and non-supercritical liquid components wherein the step of isolating comprises suspending the precipitated particulate pharmaceutical product in a non-supercritical fluid".

In contrast to applicant's claimed invention, wherein the step of isolating comprises suspending the precipitated particulate pharmaceutical

product in a non-supercritical fluid, Subramanian's process removes the separates the precipitated drug from the solvent/antisolvent, as is described below:

"The supercritical effluent from chamber 32 is then transported and fed to the high pressure separation vessel 42 via line 80. Referring to FIG. 2, the feed stream (which contains the solvent, CO<sub>2</sub>, and drug particles) enters through inlet 62 and into filter 56. Pure CO<sub>2</sub> (or other fluid or gas which is free of the organic solvent, such as such as pure helium or nitrogen) simultaneously enters through inlet 66 into chamber 58. Because the stream within chamber 58 (and thus outside filter 56) does not contain any solvent, a concentration gradient is created, thus causing the solvent within the feed stream to diffuse through membrane 70 and tube 72 and to be carried out of chamber 58, through outlet 68. As best shown in FIG. 3, the solid drug particles within the feed stream do not pass though membrane 70 and tube 72, thus allowing collection of those particles. The CO<sub>2</sub>/solvent stream that exits outlet 68 is then transported to collection vessel 44 via line 82 for condensation and collection of the solvent." (see column 6, lines 15-31, emphasis added)

Thus, the feed output of Subramanian (64) in Figure 2 contains only CO<sub>2</sub> and drug particles:

"The particles are then collected from the CO<sub>2</sub> stream by dropping the pressure resulting in the *separation of the particles from the stream.*" (see column 7, lines 34-36, emphasis added)

The invention claimed in this application yields a particulate pharmaceutical by suspending the precipitated particulate pharmaceutical product in a non-supercritical fluid. Subramanian process fails to isolate particulate in a non-supercritical fluid and thus does not teach every aspect of the claimed invention. Further, Subramanian's use of only supercritical fluid in the final processing step without a suspending medium would not teach, suggest or motivate one skilled in the art to perform this step with a suspending medium as the whole process itself is built around the removal of *all* non-supercritical fluid in the separation vessel. Subramanian's final isolation step is, as described above, only a pressure drop to separate the particles from the stream. The expected product of Subramanian's process is solids only, not a liquid stream.

In light of the foregoing, the claimed subject matter is neither anticipated by Subramanian, nor is it rendered obvious by this disclosure.

**2. Rejection of Claims 3 and 13 Mooted by Claim Cancellation**

Claims 3 and 13 have been rejected under 35 USC 103(a) as being anticipated by Subramanian et al. (US 6,113,795 "Subramanian") in view of Rouanet (US 5,864,923).

In light of the cancellation of claims 3 and 13 herein, this rejection is considered moot.

**CONCLUSION**

All claim rejections being addressed in full, Applicants respectfully request the withdrawal of the rejections of claims 1, 11 and 12, and the issuance of a Notice of Allowance for this claimed subject matter. Should the Examiner have any questions regarding the foregoing, Applicants respectfully requests that the Examiner contact the undersigned, who can be reached at (919) 483-9995.

Respectfully submitted,

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